

Congress of the United States
Washington, DC 20515

January 17, 2014

The Honorable Michael Froman
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Froman,

In October 2011 we wrote to Ambassador Kirk to reiterate the importance of incorporating, in the Trans Pacific Partnership (TPP), the Bipartisan Agreement on Trade Policy of May 10, 2007 (May 10 agreement). As the TPP negotiations enter what may be their final stages, we write you to emphasize the critical nature of these provisions in ensuring that free trade agreement (FTA) obligations do not undermine public health.

The May 10 agreement, which was incorporated into FTAs with Peru, Colombia, and Panama, included a number of key modifications from prior FTAs “aimed at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicine.” A core objective of these changes was to ensure that FTA obligations do not put patients in poor countries in a position in which they could have to wait longer than patients in the United States to obtain affordable life saving generic medicines.

There were several key changes. Exclusive marketing rights based on clinical trial data were limited to one five-year period that could run concurrently with such protection in the United States. Granting patent term extensions became optional. Regulatory authorities were given greater freedom to approve generic medicines by having patent disputes resolved through the legal system instead of the drug approval process. Language was included to make clear that our FTAs do not and should not prevent countries from taking measures to protect public health by promoting access to medicines for all. All these changes were designed to promote greater access to necessary life saving drugs while maintaining adequate incentive for continued innovation.

Some of our TPP partners face severe economic challenges to protecting the public health. Maintaining the flexibility provided by the May 10 agreement is critical for those partners, including Peru and Vietnam. Peru should not be pressured to give up the May 10 flexibilities contained in its existing FTA with the United States. In Vietnam, an estimated 280,000 people are living with HIV/AIDS. The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) supports 36,200 of the estimated 110,000 people who need anti-retroviral therapy. There would be significant concern if action through TPP could delay access to generic medicines, which may result in higher costs to the U.S. government to reach PEPFAR treatment goals or could result in removing patients from treatment. Since 2004, PEPFAR has spent over \$500 million in Vietnam to support comprehensive HIV/AIDS prevention, treatment, and care,

and the UN Global Fund, which also receives U.S. government support, has contributed over \$150 million for HIV/AIDS. We cannot squander this investment.

TPP partners also need to be equipped to address non-communicable diseases. Non-communicable diseases are the leading causes of preventable death and disability, responsible for over 60% of global deaths – 80% of which occur in low and middle income countries. At one point, the World Health Organization estimated that 15% of the world's population consumes over 90% of the world's pharmaceuticals. Millions of people in the developing world lack access to life-saving medicines. According to the UN, improving access to existing medicines could save 10 million lives each year. Our trade agreements should not impede our partners in the developing world from access to these medicines. Thank you for your ongoing attention to this important issue. We look forward to working with you to preserve key medicines-related aspects of the May 10 agreement, necessary for developing countries.

Sincerely,



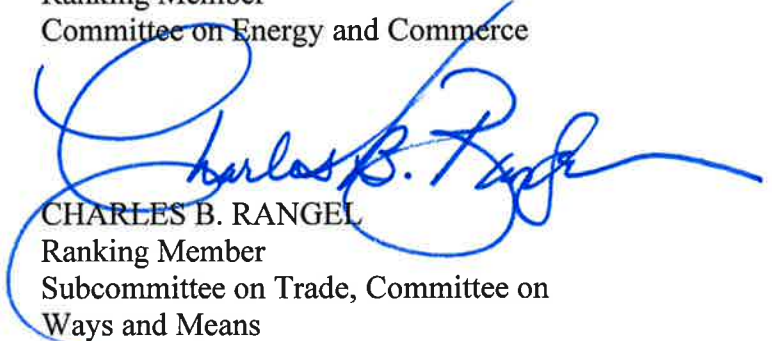
SANDER M. LEVIN
Ranking Member
Committee on Ways and Means



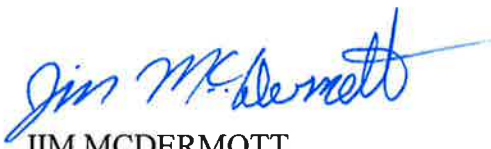
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